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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,099

04/09/2008

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149459-110072

6020

25207 7590 08/27/2010

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EXAMINER

PATEL, SHEFALI DILIP

ART UNIT

PAPER NUMBER

3767

NOTIFICATION DATE

DELIVERY MODE

08/27/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent-at@btlaw.com

Office Action Summary	Application No. 10/597,099	Applicant(s) HARDER ET AL.	
	Examiner SHEFALI D. PATEL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgments

1. In the reply, filed on May 21, 2010, Applicant amended claims 1 and 13.
2. Applicant cancelled claim 10.
3. In the non-final rejection of February 24, 2010, Examiner objected to claim 13 for a minor informality. Applicant amended claim 13. Objection is withdrawn.
4. Currently, claims 1-9 and 11-13 are under examination.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In regards to claim 1, the new term “a basic body lumen” appears to be new matter as it is not described in the specification at all or shown in the figures. It is also unclear what the difference is between the “basic body... defining a basic body lumen” and the “at least one hollow body”.

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7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 1, it is unclear what the difference is between the “basic body... defining a basic body lumen” and the “at least one hollow body”. It is unclear whether the two terms describe the same component or different components, as a “basic body... defining a basic body lumen” is a hollow body and "at least one hollow body" is a basic body with a lumen.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Sirhan et al (US 2003/0139801).

In regards to claim 1, Sirhan et al teaches an implant (Figures 1B and 4) for releasing an active substance into a vessel having a wall and a lumen through which a body medium flows, the vessel lumen defining a central axis, said implant comprising:

- a. a basic body (expandable structure [16]) comprising an interior surface (luminal facing surface [34]) defining a basic body lumen (lumen [19]), an exterior surface (tissue

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facing abluminal surface [31]) and a biodegradable material as substrate for the active substance to be released (paragraph [0022]), and around which the body medium flows on the inside of the implant

- b. a coating (therapeutic capable agent [28]) on at least a portion of the basic body interior surface facing the vessel lumen axis (Figure 1B)
- c. at least one cavity (spaces between ring segments [73] and links [76]), each cavity having an opening, wherein the opening faces toward the vessel lumen axis (Figure 4)
- d. at least one hollow body [16] which is adapted to contain the active substance (Figures 1B and 4)

In regards to claim 9, Sirhan et al teaches that the basic body [16] of the implant comprises a first, non-expanded condition and a second, expanded condition (paragraph [0020]).

In regards to claim 11, Sirhan et al teaches that the basic body [16] is tubular (Figure 4).

11. Claims 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ragheb et al (US 5,824,049).

In regards to claim 12, Ragheb et al teaches an implant for regional drug delivery (RDD), comprising: a basic body 12 comprising a biodegradable material as substrate 14 for the active substance 18 to be released, and around which the body medium flows on the inside and/or outside.

In regards to claim 13, Ragheb et al teaches that said implant is used for tumor treatment (column 8, line 45).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 2-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al, as applied to claim 1 above, and further in view of Meyer-Lindenberg et al (WO 2002/100452).

In regards to claim 2, Sirhan et al is silent about whether the basic body [16] comprises at least in part a biodegradable material selected from the group consisting of magnesium, iron, and tungsten alloy. Meyer-Lindenberg et al teaches an implant comprising magnesium alloy (Abstract). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the basic body, of Sirhan et al, with a magnesium alloy, as taught by Meyer-Lindenberg et al, as magnesium is easily degradable in the body of the patient (page 1, lines 22-23 to page 2, lines 1-2).

In regards to claim 3, in a modified implant of Sirhan et al and Meyer-Lindenberg et al, Sirhan et al is silent about whether the alloy is an alloy of the type WE. Meyer-Lindenberg et al teaches the alloy is an alloy of the type WE, a magnesium alloy containing rare earth metals and yttrium (Abstract). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the alloy, of the modified implant of Sirhan et al and Meyer-Lindenberg et al, to be an alloy of the type WE, as taught by Meyer-Lindenberg et al, as an alloy of the type WE leads to grain refinement and produces slow, continuous, and well-

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controlled corrosion development in the implant. In this fashion, excessive gas development and the risk that gas pockets form during degradation of the implant are reliably prevented (page 3, lines 13-25).

In regards to claim 4, in a modified implant of Sirhan et al and Meyer-Lindenberg et al, neither Sirhan et al nor Meyer-Lindenberg et al explicitly teaches that the alloy is of the type WE43. Meyer-Lindberg et al teaches that the alloy is an alloy of the type WE, a magnesium alloy containing rare earth metals and yttrium (Abstract). Hence, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the WE alloy, of the modified implant of Sirhan et al and Meyer-Lindenberg et al, to specifically be WE43 alloy, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Also, an alloy of the type WE leads to grain refinement and produces slow, continuous, and well-controlled corrosion development in the implant. In this fashion, excessive gas development and the risk that gas pockets form during degradation of the implant are reliably prevented (page 3, lines 13-25).

In regards to claim 5, in a modified implant of Sirhan et al and Meyer-Lindenberg et al, Sirhan et al is silent about whether the alloy contains between 1 and 30% by weight of lithium. Meyer-Lindberg et al teaches that the alloy includes 0.01 to 7 mass percent lithium and lithium increases the number of cover layer components and leads to very good corrosion protection for the magnesium alloy (page 4, lines 12-13). Meyer-Lindenberg et al does not teach the specific claimed amount of lithium, but it would have obvious to a person having ordinary skill in the art at the time the invention was made to modify the alloy to contain between 1 and 30% by weight

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of lithium, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In regards to claim 6, in a modified implant of Sirhan et al and Meyer-Lindenberg et al, Sirhan et al is silent about whether the alloy contains 0.1 to 10% by weight of aluminum. Meyer-Lindberg et al teaches that the alloy includes 0.01 to 16 mass percent aluminum and aluminum retards corrosion in an outdoor environment and also in electrolytes (page 4, lines 15-16). Meyer-Lindenberg et al does not teach the specific claimed amount of aluminum, but it would have obvious to a person having ordinary skill in the art at the time the invention was made to modify the alloy to contain between 0.1 to 10% by weight of aluminum, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In regards to claim 7, in a modified implant of Sirhan et al and Meyer-Lindenberg et al, Sirhan et al is silent about whether the alloy contains between 0.01 and 2% weight of zirconium. Meyer-Lindenberg et al teaches that the alloy includes zirconium for good corrosion resistance (page 11, line 19) but is silent about the specific amount of zirconium in the alloy. However, it would have obvious to a person having ordinary skill in the art at the time the invention was made to modify the alloy to contain between 0.01 and 2% weight of zirconium, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In regards to claim 8, in a modified implant of Sirhan et al and Meyer-Lindenberg et al, Sirhan et al is silent about whether the magnesium alloy comprises at least one constituent

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selected from the group consisting of rare earth metals, yttrium, lithium, aluminum, and zirconium. Meyer-Lindenberg et al teaches a magnesium alloy containing rare earth metals (Abstract). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the magnesium alloy, of the modified implant of Sirhan et al and Meyer-Lindenberg et al, to contain rare earth metals, as taught by Meyer-Lindenberg et al, as the mixture of the rare earth metals and the magnesium alloy will lead to grain refinement and produce slow, continuous, and well-controlled corrosion development in the implant. In this fashion, excessive gas development and the risk that gas pockets form during degradation of the implant are reliably prevented (page 3, lines 13-25).

Response to Arguments

14. Applicant's arguments with respect to claims 1-9 and 11 have been considered but are moot in view of the new ground(s) of rejection, based on the insertion of subject matter not previously presented in the claims into independent claim 1.

15. Applicant did not present any arguments or amendments concerning the 35 USC 102(b) rejection of claims 12 and 13 under Ragheb et al. Hence, the rejection is maintained.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/

Examiner, Art Unit 3767

08/24/2010

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767